

**WE CLAIM:**

- 1 1. An aqueous solution of risperidone, the aqueous solution comprising:  
2 water;  
3 a therapeutically effective amount of risperidone or a pharmaceutically acceptable  
4 free risperidone base or acid addition salt of risperidone;  
5 one or more polyhydric alcohols; and  
6 one or more buffering agents configured to maintain the pH in the range of about 3  
7 to about 4..
- 1 2. The aqueous solution of claim 1, wherein the addition salt is selected from one or  
2 more of salts of risperidone with inorganic acids comprising hydrochloric, hydrobromic,  
3 sulfuric, nitric, and phosphoric acids; or organic acids comprising acetic, propanoic,  
4 hydroxyacetic, lactic, pyruvic, oxalic, malonic, succinic, maleic, fumaric, malic, tartaric,  
5 citric, methane-sulfonic, ethanesulfonic, benzenesulfonic, p-toluenesulfonic, cyclamic,  
6 salicylic, p-aminosalicylic, and pamoic acids.
- 1 3. The aqueous solution of claim 1 wherein the one or more polyhydric alcohols  
2 comprises one or more of monosaccharides, disaccharides and sugars.
- 1 4. The aqueous solution of claim 3 wherein the monosaccharide comprises one or  
2 both of glucose (dextrose) and fructose (levulose).
- 1 5. The aqueous solution of claim 3 wherein the disaccharide comprises one or more  
2 of sucrose, lactose, maltose and cellobiose.
- 1 6. The aqueous solution of claim 3 wherein the disaccharide comprises sucrose.
- 1 7. The aqueous solution of claim 3 wherein the sugars comprise one or more of  
2 ribose, glycerine, sorbitol, xylitol, maltitol, erythritol, inositol, lactitol monohydrate,  
3 propylene glycol, galactose, mannose, xylose, rhamnose, glutaraldehyde, invert sugars,  
4 mannitol, polyethylene glycol and glycerol.
- 1 8. The aqueous solution of claim 3 wherein the sugar comprises sorbitol.
- 1 9. The aqueous solution of claim 1 wherein the aqueous solution further comprises an  
2 antioxidant.

- 1 10. The aqueous solution of claim 9 wherein the antioxidant comprises one or more of  
2 antioxidants, reducing agents and antioxidant synergist.
- 1 11. The aqueous solution of claim 10 wherein the antioxidants comprises one or more  
2 of acetylcysteine, alpha tocopherol acetate, d- alpha tocopherol, dl- alpha tocopherol,  
3 ascorbyl palmitate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT),  
4 cysteine, cysteine hydrochloride and propyl gallate.
- 1 12. The aqueous solution of claim 10 wherein the reducing agent comprises one or  
2 more of ascorbic acid, calcium ascorbate, calcium bisulphite, calcium sulphite, ascorbic acid,  
3 isoascorbic acid, potassium metabisulphite, sodium ascorbate, sodium bisulphite, sodium metabisulphite,  
4 sodium sulphite, sodium thiosulphate and thioglycerol.
- 1 13. The aqueous solution of claim 10 wherein the antioxidant synergist comprises one or more  
2 of citric acid, edetic acid (EDTA) and its salts, hydroxyquinoline sulphate, phosphoric acid, sodium citrate  
3 and tartaric acid.
- 1 14. The aqueous solution of claim 1 wherein the solution further comprises one or  
2 more pharmaceutically acceptable additives.
- 1 15. The aqueous solution of claim 14 wherein the one or more pharmaceutically  
2 acceptable additives comprise one or more of preservatives, solubilizers, viscosity  
3 enhancing agents, colors and flavors.
- 1 16. The aqueous solution of claim 15 wherein the preservative comprises one or more  
2 of benzoic acid, sorbic acid, methyl paraben or salts thereof, propyl paraben or salts  
3 thereof, benzyl alcohol and benzylalkonium chloride.
- 1 17. The aqueous solution of claim 1 wherein the buffering agent comprises an acid-  
2 base combination.
- 1 18. The aqueous solution of claim 17 wherein the acid comprises one or more of  
2 succinic, tartaric, lactic, or citric acid and base is sodium hydroxide or disodium hydrogen  
3 phosphate.
- 1 19. The aqueous solution of claim 17 wherein the acid is tartaric acid and base is  
2 sodium hydroxide.

- 1 20. The aqueous solution of claim 15 wherein the flavors comprise one or more of  
2 vanilla, cherry, raspberry, black currant, strawberry, caramel chocolate, Mint Cool and  
3 Fantasy flavors.
- 1 21. A process for the preparation of an aqueous solution, the process comprising:  
2 mixing water, a therapeutically effective amount of risperidone or a  
3 pharmaceutically acceptable free risperidone base or acid addition salt of risperidone, one  
4 or more polyhydric alcohols; and one or more buffering agents configured to maintain the  
5 pH in the range of about 3 to about 4.
- 1 22. A method for the management or treatment of the manifestations of psychotic  
2 disorders in a mammal, the method comprising administering an aqueous solution  
3 comprising water; a therapeutically effective amount of risperidone or a pharmaceutically  
4 acceptable free risperidone base or acid addition salt of risperidone; one or more  
5 polyhydric alcohols; and one or more buffering agents configured to maintain the pH in  
6 the range of about 3 to about 4.